grams sodium chloride, 0.5 gram Certified Reagent Acid Fushsin, 1,000 milliliters distilled water) is then pumped through the infusion needle at a rate of 50 milliliters per hour. The test shall be terminated when the tampon is saturated and the first drop of fluid exits the apparatus. (The test result shall be discarded if fluid is detected in the folds of the condom before the tampon is saturated). The water is then drained and the tampon is removed and immediately weighed to the nearest 0.01 gram. The absorbency of the tampon is determined by subtracting its dry weight from this value. The condom shall be replaced after 10 tests or at the end of the day during which the condom is used in testing, whichever occurs first. --

REMARKS

Applicants' Attorney wishes to thank the Examiner for granting a phone interview on September 14, 2002.

In the Claims

Claims 1-4, 15 and 16 are now pending. Claims 1, 15, and 16 have been amended. Claim 1 was amended to clarify that the generally cylindrical self-sustaining form has the specified diameter. Claims 15 and 16 were amended to state that the tampon demonstrates the rate of expansion claimed. No new matter was added by these clarifying amendments.

In the Specification

The specification has been amended to recite details of the standard syngyna test. As discussed in greater detail below, the Examiner agreed in a phone interview that inclusion of this information does not constitute new matter.

OBJECTIONS/REJECTIONS

The amendment filed 7/6/01 was objected to under 35 USC 132 as introducing new matter into the disclosure. The specification was also objected to under 37 CFR 1.71 as failing to provide support as filed for the amendment. The Office Action requires Applicants to cancel the new matter. Applicants' Attorney spoke with the Examiner regarding this matter. Applicants' Attorney suggested that the names of the prior art tampons are not a part of the invention, but rather are included to assist the reader in recognizing the improvements offered by the present invention over the prior art. Moreover, it was discussed that it is irrelevant which prior art tampon is which. Applicants' Attorney also pointed out that the labeling on the other tables is not in conflict with the amended table; merely different. Thus, three possible solutions were discussed. First, Applicants could amend the labeling to merely state

"Prior Art tampon A, Prior Art tampon B", etc. Second, Applicants could delete the prior art data entirely and submit it for the Examiner's review via a 1.32 declaration if deemed probative at a later date since it is not essential to describe the present invention. The third option would result in entering the preliminary amendment and supporting the labeling changes with a 1.32 declaration. Applicants have chosen the third option and submit herewith a declaration from the supervisor of the team responsible for collecting the data. The declaration verifies that the changes in the labeling are correct. The Examiner agreed that correcting the mislabeled table in this fashion would not be deemed new matter if it clearly only corrected the labeling of prior art tampons. Thus, since the amendment relates only to the labeling of prior art tampons tested and since the declaration submitted herewith verifies this is the correct labeling, Applicants have not canceled matter added by the preliminary amendment filed July 2, 2001. Applicants respectfully request entry of the preliminary amendment dated July 2, 2001 and removal of these objections.

The specification was also objected to as failing to provide an adequate written description of the invention. The Examiner states that the standard syngyna test has not been disclosed. During the telephone interview, the Examiner maintained the position that the test constitutes essential subject matter since the claims directly reference the test. The Examiner also took notice of the fact that the standard syngyna test discussed in the specification is a well known industry standard. The Examiner further stated that since it was clear what governmental test Applicants were referring to, inclusion of details of the test method does not constitute new matter. Accordingly, Applicants have amended the specification to include a portion discussing the standard syngyna test in detail. For the Examiner's convenience, Applicants have included a copy of 21 CFR 801.430 in its entirety. Therefore, Applicants respectfully request withdrawal of this objection.

The Examiner also states that one of ordinary skill in the art would not be able to make the claimed invention, stating that one would have to guess what materials and structural configuration would provide the claimed test results. Thus, the Examiner states that the specification is non-enabling. The Examiner rejects Claims 1-4, 15, and 16 under 35 USC 112, first paragraph as not being enabled for the same reason as stated in the objection to the specification. Specifically, the Office Action asks how the expansion is accomplished, what is the starting density or level of compression of the tampon, how much is it compressed to get the claimed result, and what fibers are used.

Applicants submit that one of ordinary skill in the art would not have to undergo undue experimentation in order to make tampons according to the present invention. The specification discusses the factors by which the desired expansion is accomplished at page 15, line 21 through page 17, line 14. Specifically, the dimensions of the tampon pledget prior to compression are discussed as being important (e.g. starting with a shorter length) as well as the manner of conditioning and compression (compressed primarily in the widthwise direction with very minimal axial compression). Even more specifically, page 17, lines 30-35 provide very specific width and length measurements for various absorbencies for the tampons reported in the tables. Applicants submit that the level of compression flows naturally from the starting measurements given above, the final desired tampon diameters (e.g. an insertable size such as the dry diameters provided in Table 1), and the starting material. Applicants further submit that the starting material is specified such that one of ordinary skill in the art need not undergo undue experimentation in making tampons of the present invention. In fact, one of ordinary skill in the art is directed to simply use materials similar to those currently used for tampons since they have advantages of proven record of suitability for human use, etc. (*See* page 3, lines 24-27 and page 12, lines 4-6). More specifically, page 10, lines 18-32 and page 11, lines 1-8 list possible materials and specific fibers. Even more specifically, referring to the tampons in the tables for which specific width and length measurements were provided, page 18, lines 1-8 discuss preferred materials and specific rayon to cotton fiber percentages for the various absorbencies. Thus, Applicants submit that the specification does enable the claims as it sets forth starting dimensions of the uncompressed pledget, final dimensions of the tampon, and materials to be used including fiber types and blends – even simplifying by allowing one to start from prior art tampon materials/webs. Applicants therefore respectfully request withdrawal of the objection to the specification and of the rejection of the claims.

Claims 1-4, 15, and 16 are rejected under 35 USC 112, second paragraph, as being indefinite. With respect to Claim 1, the Examiner is confused as to what has the claimed diameter. Applicants have amended Claim 1 in an effort to clarify that the generally cylindrical, self-sustaining form has the claimed diameter.

With respect to Claims 15 and 16, the Examiner points out that the element which demonstrates the claimed rate of expansion has been omitted from the claim language. Applicants have amended Claims 15 and 16 to correct this inadvertent omission, identifying that it is the tampon that has the claimed rate of expansion.

C

Finally, the Examiner questions why the expanded diameter for prior art tampon D is not provided in the specification. Applicants did not make the "missing" measurements for tampon D since they had no reason to believe they would fall within the claims of the present invention. Specifically, Applicants noted that the width under pressure for tampon D's Super Plus tampon was amongst the lowest of measurements taken (22mm) and felt no need to test the Super and Regular absorbencies.

CONCLUSIONS

All of the relevant rejections and objections in the Office Action have been discussed. No new matter has been added by the Amendment.

In light of the amendments contained herein, Applicants respectfully request reconsideration of all rejections and allowance of all claims. Early and favorable action is respectfully requested.

Respectfully submitted,

By Kirsten K Stone

Kirsten K. Stone
Attorney for Applicant(s)
Registration No. 42,129
(513)-634-5662

Oct. 2 2002
Cincinnati, Ohio
Case 8312

C

[redacted]

Version with Markings to Show Changes Made

1.(Twice Amended) An absorbent tampon comprising:

a mass of absorbent material which has been compressed into a generally cylindrical, self-sustaining form, wherein subsequent to said compression said generally cylindrical, self-sustaining form ~~absorbent material~~ has a diameter of less than about 15 mm, said tampon having an absorbent capacity as measured by the syngyna test of between about 6 to about 9 grams, said tampon being fluid expanding, and said tampon having an expanded width upon fluid absorption of at least about
20 mm.

15. An absorbent tampon comprising:

a mass of absorbent material which has been compressed into a generally cylindrical, self-sustaining form, wherein said tampon has an absorbent capacity as measured by the syngyna test of between about 6 grams and about 9 grams, and wherein said tampon demonstrates a rate of expansion as measured by the expansion under pressure test from time zero until two minutes of at least about 1.25 mm/min.

16. An absorbent tampon comprising:

a mass of absorbent material which has been compressed into a generally cylindrical, self-sustaining form, wherein said tampon has an absorbent capacity as measured by the syngyna test of between about 6 grams and about 9 grams, and wherein said tampon demonstrates a rate of expansion as measured by the expansion under pressure test from time zero until seven minutes of at least about 0.58 mm/min.

C